

Year 2000 Readiness Assessment Survey

(A Special Year 2000 Data Gathering Request)

Name of Company: _____
Address of Company: _____

(If this report covers divisions, subsidiaries or affiliates of this firm whose products are or have been marketed under names that are different from the parent company, please identify all of these divisions, subsidiaries or affiliates on the attachment provided below.)

Name of Y2K Coordinator (or contact): _____
Title of Y2K Coordinator (or contact): _____
Phone Number: _____
E-mail address: _____

1. Has your company developed a comprehensive plan and are you taking the appropriate steps, within your control, to assure that the information technology and automated systems used to produce products and distribute products in the United States will be Y2K compliant and therefore continue to function as intended after December 31, 1999?¹
_____Yes _____No

Further information to support this summary statement of readiness is provided by indicating the status of your preparations with regard to each of the Y2K preparation program activities listed below. Please check the appropriate response and provide dates when relevant.

Y2K Program Phase

(See the instructions for a description of each phase.)

Company Status

a. Awareness and Assessment

- ___ Completed
___ Underway, expected completion date of
(insert date _____).
___ Not started, planned completion date of
(insert date _____).
___ Not a part of our Y2K program

¹ By responding to this survey, you agree to allow FDA to make the response to this portion of question 1 of the survey public, along with the name of your company responding to the survey. All other responses to this survey, including those to Questions 1a through 1e, will be protected under Section 4(f) of the Year 2000 Information and Readiness Disclosure Act

Survey response from (enter company name):

b. Renovation or Development of
Alternative Solutions.

- ☐ Completed
☐ Underway, expected completion date of
(insert date_____).
☐ Not started, planned completion date of
(insert date_____).
☐ Not a part of our Y2K program

c. Testing and Validation of Renovations,
New Systems or Alternative Solutions.

- ☐ Completed
☐ Underway, expected completion date of
(insert date_____).
☐ Not started, planned completion date of
(insert date_____).
☐ Not a part of our Y2K program

d. Implementation of New Systems
or Renovated Systems or
Alternative Solutions.

- ☐ Completed
☐ Underway, expected completion date of
(insert date_____).
☐ Not started, planned completion date of
(insert date_____).
☐ Not a part of our Y2K program

e. Development of Contingency Plans.

- ☐ Completed
☐ Underway, expected completion date of
(insert date_____).
☐ Not started, planned completion date of
(insert date_____).
☐ Not a part of our Y2K program

(Please provide an update to FDA when, in your judgment, any significant change to your firms status occurs. An example of a significant change would be completion of one of the phases previously indicated as "not started" or a problem which delays preparations for continued production of an essential product for which your firm is the sole source or the principal source.)

2. Do you plan on having an independent organization (i.e., a group other than the one that did the initial analysis or conducted the activity) review all or portions of your Y2K preparation activities?

- ☐ Yes (When will this independent review be completed?
(Insert date_____))
☐ No

Survey response from (enter company name):

3. Do you have foreign suppliers of essential materials or components used in the manufacture of your products sold in the United States?

_____Yes _____No

If the answer to the above is yes, have you asked these foreign suppliers about their Y2K readiness?

_____Yes

_____No (When will this task be completed? (insert date_____))

4. If you have substantially completed development of contingency plans (as indicated in 1.e.):

- a. Have the contingency plans been tested where feasible?

_____Yes

_____No (When do you expect to complete testing? _____)

_____Testing not planned

- b. Do the contingency plans address potential problems with your key business partners (utilities, service providers, suppliers, vendors, distributors)?

_____Yes _____No

- c. Do your contingency plans address potential problems with foreign suppliers (e.g., establishment of alternate suppliers)?

_____Yes _____No

5. In the event of an unexpected increase in demand for products essential for healthcare due to Y2K concerns on the part of customers or in response to actual production or supply problems encountered by other suppliers of similar products, is an increase in your production feasible?

_____Yes _____No

- a. Do you have plans to increase production of any of your products, which could be considered essential to the delivery of healthcare, due to an anticipated increase in customer demand as a result of Y2K concerns?

_____Yes _____No

Survey response from (enter company name):

Additional Comments - Y2K Readiness

Please provide additional specific comments on your firm's Y2K readiness or compliance status if appropriate. (Use additional pages if necessary.) For example, provide additional explanations for the responses to questions 1 through 5 that may be needed to explain special circumstances. Identify any essential medical supply for which your firm is the sole or principal supplier. Provide information on any product type whose availability may be compromised by anticipated supplier or component vendor problems.

Comments:

Additional Comments - Special Concerns

In addition, please provide comments on special concerns that you have or which may be warranted regarding essential medical supplies whose availability could be placed in jeopardy due to Y2K problems. (Use additional pages if necessary.) For example, if there are specific product lines which may be especially vulnerable due to reliance on external suppliers or due to delays in upgrading production facilities, please describe them.

Comments:

Signature of the President or Chief Executive Officer
or other Responsible Corporate Official

Date

Survey response from (enter company name):

Attachment - Listing of Divisions, Subsidiaries and Affiliates

Information regarding divisions, subsidiary or affiliate organizations: The Y2K readiness status of all divisions or subsidiaries is to be reflected in this survey response for the parent or owning firm. When divisions or subsidiaries, marketing under different trade or brand names, are included in the survey response, please identify the divisions and subsidiaries on the form provided below for that purpose.

Name of division, subsidiary or affiliate	Brand or trade names used if different from name of reporting company	Location (City and State)
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

Public reporting burden for this collection of information is estimated to average 13 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing this burden to:

Year 2000 Coordinator (HFZ-140)
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.